

REMARKS

Rejection of the claims under 35 USC § 112:

Claims 1, 4-6, 10, and 13-14 have been rejected under 33 U.S.C. 112, first paragraph as failing to comply with the written description requirement for containing new matter. It is the Examiner's position that the specification does not disclose or contemplate a "reversibly modified RNA consisting of at least one hydrophobic group having one to twenty carbon atoms covalently linked to said RNA." Applicants respectfully disagree. Applicants have shown reversible modification of RNA with hydrophobic groups having 1, 3, 11, and 20 carbon atoms (Figures 1-2 and examples 1-4). These examples show hydrophobic groups at the lowest and highest ends of the claimed range as well as hydrophobic groups within the claimed range. Applicants request reconsideration of the rejection.

It is further the Examiner's position that the specification does not contemplate the limitation "wherein association of the reversibly modified RNA with the transfection reagent is enhanced via hydrophobic interactions between the hydrophobic group linked to the RNA with a hydrophobic part of the amphipathic transfection reagent". As per the interview with the Examiner on 1 October 2010, Applicants have amended the claim to clarify the interaction between the modified RNA and the transfection reagent. Support for the amendment can be found in the specification as originally filed as follows:

page 3 lines 24-39, "In a preferred embodiment, we describe methods to alter the interaction of an siRNA with a cell or transfection agent comprising: reacting the siRNA with a modifying agent wherein the modifying agent contains a hydrophobic group. ... Hydrophobic modification of the siRNA allows hydrophobic interaction of the siRNA with the transfection agent."

page 9 lines 11-15, "The RNA modification may facilitate the interaction of the RNA with the lipid or polymer. For example, hydrophobic modification of an RNA can enhance interaction of the RNA with an amphipathic compound through hydrophobic interactions."

page 4 lines 9-11: "Modification of the RNA, such as with a hydrophobic group, makes it possible to interact the nucleic acid with a polymer via non-ionic interactions." (*hydrophobic interactions are non-ionic*)

In view of the amendments and arguments, Applicants request reconsideration of the §112 rejection.

Rejection of the claims under 35 USC § 102:

Claims 1, 4-6, 10, 13, and 14 have been rejected under 35 U.S.C. 102(e) as being unpatentable over Fosnaugh et al. (U.S. 2003/0143732) as evidenced by Thierry et al. (US 6,110,490). Applicants respectfully disagree. It is the Applicants' opinion that Fosnaugh et al. do not teach the combination of an RNA to which a hydrophobic group is reversibly attached associated with an amphipathic transfection reagent wherein the modified RNA interacts with the amphipathic transfection reagent via hydrophobic interaction between the hydrophobic group linked to the RNA and a hydrophobic part of the amphipathic transfection reagent.

Applicants' claim is neither understood or taught by '732 so as to be intelligently reproduced. "A prior use, in order to negative novelty, must be something more than an accidental or casual one. It must, indeed, be so far understood and practiced, or persisted in, as to contribute to the sum of human knowledge and be accessible to the public, becoming an established fact in the art." (Anthracite Separator Co. v. Pollock). For one skilled in the art to combine separately disclosed parts taught by '732 would be "purely a matter of chance and not the inevitable result of its process." (International Nickel Co. v. Ford Motor Co.) and therefore not an anticipation. There is no specific teaching in the '732 that would lead to Applicants' invention. Therefore, it is the Applicants' opinion that '732 patent is not enabling and fails to describe the Applicants' instant invention sufficiently to enable a person of ordinary skill in the art to carry out Applicants' invention. Applicants request reconsideration of the §102 rejection.

Rejection of the claims under 35 USC § 103:

Claims 1, 4-6, 10, 13, and 14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Fosnaugh et al. (U.S. 2003/0143732) or Lewis et al. (US 20030143201), taken with Manoharan, M. (Biochimica et Biophysica Acta 1489, 1999: 117-130) and Goldsborough (WO 01/94626). It is the Applicants' opinion that the amendments and arguments made above in response to the §102 rejections are sufficient to overcome the §103 rejections.

The Examiner's rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 1, 4-6, 10, 13, and 14 should be allowable.

Respectfully submitted,

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I hereby certify that this correspondence is being
transmitted to the USPTO on this date: 5 Oct. 2010.

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